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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,102	ERLENBACH ET AL.	
	Examiner	**Art Unit**	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 17 October 2005.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-47 is/are pending in the application.
 4a) Of the above claim(s) 11 and 20- 45 is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) 1-10,12-19,46 and 47 is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a)☐ All b)☐ Some * c)☐ None of:
  1.☐ Certified copies of the priority documents have been received.
  2.☐ Certified copies of the priority documents have been received in Application No. _____.
  3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 1 to 47 are pending in the instant application. Claims 1, 12 and 13 have been amended and claims 46 and 47 have been added as requested by Applicant in the correspondence filed 17 October of 2005.

2) Claims 11 and 20 to 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 17 October of 2005. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Whereas claim 11 was not included with claims 20 and 21 in the original requirement, claims 1 to 19 were identified as being drawn to "an isolated taste receptor" that is distinct from claims 20 and 21, which were identified as being drawn to "a recombinant cell expressing a taste receptor". Because claim 11 is expressly drawn to the same subject matter as claims 20 and 21, it clearly was intended to be included therewith.

3) Claims 2, 3, 9, 14, 15, 46 and 47, in so far as they relate to other than SEQ ID NO:15, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 17 October of 2005. Applicant has traversed the requirement on the premise that "a search regarding the proteins of SEQ ID NOS: 15, 20, 23, and 25 has already been conducted within the United States Patent and Trademark Office regarding a related case". Applicant's reference to "a related case entitled "Mammalian Sweet Taste

Receptors," bearing U.S. Application Number 09/927,315, filed on August 10, 2001" in traversing the restriction requirement in the instant application is immaterial to the instant requirement. In the decision of *In re Hutchison*, 69 USPQ 138 (CCPA, 1946), the court held that

> "We are not concerned, of course, with the allowed claims in either the patent or in this application. The sole question for our determination is whether the six article claims on appeal were properly rejected below, and this we pass upon without further reference to, and without comparing them with, the claims in the patent or the claims which stand allowed in this application."

In essence, the position that each application is examined on its own merits can be found in the judicial precedent cited above.

Further, 37 C.F.R. 1.78(1)(i)&(ii) states that, except for a continued prosecution application filed under § 1.53(d), any nonprovisional application claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross references to other related applications may be made when appropriate (see § 1.14). This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), as is the instant application, **this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application**. These time periods are not extendable. It is noted that the instant application was filed more than two years before the mailing date of the instant Office Action and does not contain such a reference. Except as provided in paragraph (a)(3) of this section, the **failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application**. Because the prior application referred to by Applicant is not "related" to the instant application, as shown by the absence of any reference to such a relationship in the instant application, Applicant's reliance on the prosecutorial history in that prior application in traversing the instant requirement is improper.

The requirement is still deemed proper and is therefore made FINAL.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claims 1, 4 to 10, 12, 13, 16 to 19 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. These claims encompass subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification fails to provide an adequate written description of the genus of proteins that are encompassed by the limitation "T1R3 polypeptide". In fact, the only "T1R3 polypeptides" that are described in the instant specification in terms that demonstrate possession of the claimed invention are "T1R3" polypeptides

comprising the entire amino acid sequence presented in any of SEQ ID NO:15, 20, 23, 25 or 31 of the instant application. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Whereas the instant specification provides a detailed description of five isolated DNAs encoding five very specific taste receptors having very specific physical and structural properties, the instant specification does not provide a structural formula which is definitive of all of the members of the genus of proteins encompassed by the term "T1R3 polypeptide" as that limitation is defined in the instant specification. Whereas the instant specification may identify some properties which are common to the odorant receptors that are disclosed in the instant specification, it does not identify those defining structural elements which provide the functional and structural properties of a sweet taste receptor.

5) Claims 1, 4 to10, 12, 13, 16 to19 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims encompass a "T1R3 protein" having other than the entire amino acid sequence presented in SEQ ID NO:15, 20, 23, 25 or 31 of the instant application. The text on page 12 of the instant specification indicates that the term "T1R3 polypeptide" encompasses a polypeptide having at least 60% sequence identity to at least 25 amino acids of the sequence presented in SEQ ID NO: 15, 20, 23, 25 or 31 of the instant application. That text indicates that this term encompasses non-naturally occurring proteins whose amino acid sequences deviate from SEQ ID NO: 15, 20, 23, 25 or 31 by as many as 837 out of 852 amino acid residues. However, the instant specification does not provide the guidance needed to use a "T1R3 polypeptide" comprising anything less than the entire amino acid sequence presented in SEQ ID NO: 15, 20, 23, 25 or 31. The only manner described in the instant specification of using the claimed protein in a specific and substantial application is in the identification of compounds that have potential use because of their ability to agonize or antagonize one of the human "T1R3 proteins" described therein. The claimed invention is only useful in so far as the "T1R3" protein employed in such an assay responds in a manner that is predictive of an authentic

physiological response. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

One of ordinary skill in the art of receptor biology would not reasonably believe that the majority of physical peptide embodiments having at least 60% sequence identity to at least 25 contiguous amino acids from SEQ ID NO: 15, 20, 23, 25 or 31 of the instant application are going to be functional, much less be capable of producing an authentic response. Because the instant specification does not identify those amino acid residues in SEQ ID NO: 15, 20, 23, 25 or 31 which are critical to the structural and functional integrity of a sweet taste receptor protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an intentionally modified "T1R3" protein of the instant invention, an artisan can not change even a single residue within the amino acid sequence of SEQ ID NO: 15, 20, 23, 25 or

31 and predict the effects of that change on the performance of that protein "by resort to known scientific law". Unless one can predict, with reasonable confidence, that an intentionally modified "T1R3" protein is going to produce a response that is predictive of a native human "T1R3" protein, the information obtained from a process that uses that modified protein is of no practical value.

6) Claims 1, 4 to10, 12, 13, 16 to19, 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims are not enable because they require a nucleic acid that encodes a "T1R3 polypeptide" and that hybridizes to a nucleic acid that also encodes a "T1R3 polypeptide". Because nucleic acids only hybridize to complementary nucleic acids, these claims require a nucleic acid that encodes a "T1R3 polypeptide' in both its sense and antisense direction, and no such nucleic acid is adequately described in the instant specification, which also fails to provide the guidance needed to produce it.

The following is a quotation of the second paragraph of 35 U.S.C.112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7) Claims 1 to 10, 12 to19, 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7.1) Claim 1 is vague and indefinite because the limitation "two T1R3 polypeptides" is not a proper antecedent basis for "the T1R3 polypeptide".

7.2) Claims 1 to 10,12 to 19, 46 and 47 are vague and indefinite in so far as they employ the term "T1R3 polypeptide" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "T1R3 polypeptide" an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. The definition of this term provided on page 12 of the instant specification is notably vague and indicates that this terms includes "nucleic acid and polypeptide polymorphic variants, alleles, mutants, and interspecies homologs that are members of the TIR family of G protein coupled receptors" and "polypeptides having an amino acid sequence that has greater than about 60% amino acid sequence identity" "preferably over a region of over a region of at least about 25" "or more amino acids". Given the remarkably vague definition provided by the instant specification, it would be impossible for an artisan to determine if any protein was encompassed or excluded by this limitation.

7.3) Claims 1 and 13 are vague and indefinite because the limitation "highly stringent hybridization conditions" is conditional and no single set of defining conditions has been provided by the claims or the specification. In fact, outside of the claims, this term could not be found in the instant specification. Claims 2 to 10, 12, 14 to 19 , 46 and 47 are vague and indefinite in so far as they depend from either of claims 1 or 3 for this element.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8) Claims 1 to 4, 6 to 10, 12 to 19, 46 and 47are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Li et al. publication (P.N.A.S. 99(7):4692-4696, 02 Apr. 2002). The amino acid sequence of the protein identified in Figure 1 on page 4693 of Li et al. as hT1R3 is identical to the amino acid sequence presented in SEQ ID NO:15 of the instant application. The HEK-293-derived cells described therein that were "transfected with T1R3 alone" produced an isolated homodimeric taste receptor that is fully encompassed by the instant claims. That taste receptor was "isolated' because it was free from the taste-associated proteins with which it is found in nature. The fact that it was homodimeric would have been a property inherent thereto. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product.

In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Claims were directed to a titanium alloy containing 0.2-0.4% Mo and 0.6-0.9% Ni having corrosion resistance. A Russian article disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but was silent as to corrosion resistance. The Federal Circuit held that the claim was anticipated because the percentages of Mo and Ni were squarely within the claimed ranges. The court went on to say that it was immaterial what properties the alloys had or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties.). See also *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971) (Claim 1 was directed to a parachute canopy having concentric circumferential panels radially separated from each other by radially extending tie lines. The panels were separated “such that the critical velocity of each successively larger panel will be less than the critical velocity of the previous panel, whereby said parachute will sequentially open and thus gradually decelerate.” The court found that the claim was anticipated by Menget. Menget taught a parachute having three circumferential panels separated by tie lines. The court upheld the rejection finding that applicant had failed to show that Menget did not possess the functional characteristics of the claims.); Northam Warren Corp. v. D. F. Newfield Co., 7 F. Supp . 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.). See M.P.E.P. 2112.01

9) Claims 1 to 4, 6 to 10, 12 to 19, 46 and 47 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Adler et al. patent (US 6,955,887 B2). The amino acid sequence presented in SEQID NO:6 of Adler et al. is identical to the amino acid sequence presented in SEQ ID NO:15 of the instant application. Example 7 in column 48 of Adler et al. described the transfection of HEK-G15 cells with hT1R2 and hT1R3 "individually and in combination".

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10) Claims 1 to 10, 12 to 19, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of the Li et al. publication (P.N.A.S. 99(7):4692-4696, 02 Apr. 2002) or the Adler et al. patent (US 6,955,887 B2). In so far as these claims encompass a T1R3 protein preparation that has been isolated from the cell producing it, the purification of a membrane preparation containing a recombinantly expressed receptor protein of interest for the purposes of conducting binding studies and for use as an immunogen for the production of antibodies to that protein was a practice that was very old and very well known in the art of receptor biology by the time of the instant invention as evidenced by the text on pages 23, 24 and 29 to 32 of the instant specification. The purification of T1R3 protein of each of the Li et al. and Adler et al. references by employing those routine methods in the art to facilitate the further characterization of that protein would have been *prima facie* obvious to one of ordinary

skill in the art of receptor biology in view of either of those references. Further, the use of crosslinking agents such as glutaraldehyde to covalently crosslink and thereby facilitate the purification of protein complexes in their native subunit configuration to determine the stoichiometric nature of that complex was also a routine practice in the art at the time of the instant invention. Given that each of these references described the criticality of the subunit composition of taste receptor described there ands the failure of T1R3 alone to respond to ligand in a manner similar to a T1R1/T1R3 or a T1R2 /T1R3 complex, one would have been motivated to covalently crosslink and purify T1R3 protein complexes in a cell expressing only that receptor to determine if it was, in fact, forming protein complexes of a proper stoichiometric configuration by employing those routine methods.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1600